

IS 16127 : 2013

(Reaffirmed 2016)

(Reaffirmed 2019)

भारतीय मानक

कान के पीछे लगाए जाने वाले श्रवण
सहायक यंत्र — डिजिटल — विशिष्टि

Indian Standard

BEHIND THE EAR (BTE) HEARING
AIDS — DIGITAL — SPECIFICATION

ICS 33.160.25

© BIS 2013

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

October 2013

Price Group 4

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Audio, Video and Multimedia Systems and Equipment Sectional Committee had been approved by the Electronics and Information Technology Division Council.

There is no ISO/IEC standard on this subject.

The Committee responsible for the formulation of this standard has reviewed the provisions of the international publications listed in Annex B and has decided that these may be used in conjunction with this standard till Indian Standards on these subjects are published.

The composition of the Committee responsible for the formulation of this standard is given in Annex E.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

BEHIND THE EAR (BTE) HEARING AIDS — DIGITAL — SPECIFICATION

1 SCOPE

This standard specifies the general and performance requirements of the BTE hearing aids — digital, which connects to the ear by means of an ear.

2 REFERENCES

The standards listed in Annex A and Annex B contain provisions, which through reference in this text constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreement based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A and Annex B.

3 TERMINOLOGY

For the purpose of this standard, the terms and definitions given in 2 of IS 10776 (Part 1) : 1984 and the following shall apply

3.1 Behind the Ear (BTE) Hearing Aid — Digital —

A hearing aid normally worn behind the ear of a person, which gets connected to the ear by means of an ear tip or ear mould and incorporates built-in digital processing.

4 CHARACTERISTICS OF BTE TYPE HEARING AID — DIGITAL

The characteristics of hearing aid are as follows:

Sl No. (1)	Characteristics (2)	Requirements (3)
i)	Maximum OSPL 90	105 - 135 dB SPL
ii)	HF average OSPL 90	100 - 135 dB SPL
iii)	HD average full on gain (at 50/60 dB input)	40 dB <i>Min</i>

5 GENERAL REQUIREMENTS

5.1 Design and Workmanship

5.1.1 Guiding Principles of Design

It is recommended that the hearing aid should be designed to,

- a) avoid undesirable feedback;
- b) minimize interference resulting from the

proximity of the hearing aid to the source of electrical interference;

- c) minimize effect due to body perspiration;
- d) ensure that under normal conditions of use, it shall not be possible to damage the hearing aid by inserting the battery with the polarity reversed;
- e) ensure that the working voltages and current of all components shall not exceed the manufacturer's ratings for these components; and
- f) minimize the surface noise and EMI/EMC and ensure that there are no sharp corners on body of hearing aid.

5.2 Power Supply

The hearing aid shall be so designed as to be capable of operation from a battery of nominal voltage 1.3 V.

5.3 Housing

5.3.1 The battery compartment shall be distinctly and indelibly marked to indicate the polarity (+ve) of battery connections. An ear insert (or soft ear tip with an elbow and tube/prebent tube) shall also be provided with each hearing aid.

5.3.2 Dimensions

The maximum permissible dimension for BTE hearing aids (without an ear tip/mould) are as follows:

Overall length	: 60 mm
Overall width	: 25 mm
Thickness	: 15 mm

5.3.3 Mass

The mass of hearing aid excluding the battery ear insert and adopter, if any, shall not exceed 10g, excluding the ear tip/mould.

5.4 External Case

Each hearing aid complete with the ear insert shall be supplied in an external carrying case of durable quality.

5.5 Controls

5.5.1 The following controls shall be provided on each hearing aid:

- a) 'ON — OFF' switch, to apply power either through a switch or through the battery compartment cover/door;

- b) Gain control with appropriate marking shall be provided; and
- c) Provision for adjusting tone either by a tone control or through programming.

5.5.2 Marking of Control Setting on Hearing Aids

Provisions of Annex C shall apply.

6 METHODS OF MEASUREMENT

The characteristics specified in this standard shall be measured in accordance with applicable trade practices and conform to IS 10776 (Parts 1 and 2) and SI No. 1 of Annex B.

7 MARKING

7.1 Each hearing aid shall be indelibly and clearly marked with the following information:

- a) Name and/or trade-mark of the manufacturer;
- b) Model; and
- c) Serial Number

7.2 BIS Certification Marking

The hearing aid and/or the hearing aid manual may also be marked with the Standard Mark.

7.2.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which a licence for the use of the Standard Mark may be granted to the manufacturers or producers may be obtained from the Bureau of Indian Standards.

7.3 Each hearing aid must be packed with an instruction manual to furnish,

- a) name or trade-mark of the manufacturer;
- b) type and rating of the battery;
- c) precaution to be taken in the use of hearing aid;
- d) method of adjusting gain control; and
- e) any other useful information the manufacturer would like to furnish.

7.4 The manufacturer shall specify the maximum current consumption in the instruction manual.

8 TESTS

8.1 Classification of Tests

8.1.1 Type Tests

The procedure for type approval shall be in accordance with IS 10673 (*see Note*). The minimum number of samples for type tests shall be three. The sequence of type tests shall be as given in Table 1. There shall be

no single failure in any of the type tests. If any failure occurs in the type tests, twice the number of samples shall be subjected to type tests. There shall be no single failure in any of the type tests.

NOTE — Recommendation for type approval and a sampling procedure for electronic components

8.1.2 Acceptance Tests

The acceptance tests shall be carried out based on sampling plan as given in Annex D. The hearing aids shall be subjected to the following tests in the order given below:

- a) Maximum saturation sound pressure level;
- b) HF Average OSPL 90;
- c) Frequency range;
- d) HF — average full on gain;
- e) Total harmonic distortion;
- f) Internal noise from the hearing aid in terms of equivalent input noise level; and
- g) Battery current.

8.1.3 Routine Tests

Each and every hearing aid shall be subjected to the following tests:

- a) Maximum saturation sound pressure level;
- b) HF Average OSPL 90;
- c) HF — average full-on gain;
- d) Frequency range; and
- e) Total harmonic distortion.

8.2 Test Schedule

The test schedule for the performance characteristics, its methods of measurements and the requirements to be met are given in Table 1.

9 RECOMMENDED GOOD MANUFACTURING PRACTICES

9.1 Under normal conditions of use, it should not be possible to damage the hearing aid by inserting the batteries with polarity reversed.

9.2 Working voltages and currents in all components should not exceed the manufacturer's ratings for these components.

9.3 Use of mercury batteries is not desirable.

9.4 Housing

The hearing aid including the battery should be contained in compact lightweight housing of a size easily carried on a person. The design should be such as to provide for hearing aid reasonable protection from dust.

Table 1 Test Schedule Requirements
(Clauses 8.1.1 and 8.2)

SI No. (1)	Characteristics (2)	Requirement (3)
i)	Maximum OSPL 90	105-135 dB SPL Maximum OSPL 90 of > 135dB SPL is likely to damage the ear, hence should be prescribed under supervision of qualified audiologist
ii)	HF average OSPL 90	100-135 dB SPL
iii)	HF average full on gain (at 50/60 dB input)	40 dB <i>Min</i>
iv)	Frequency range	105-115 dB : 200-4 500 Hz 115-135 dB : 200-4 000 Hz
v)	Effect of tone control positions on frequency response	As specified by the manufacturer
vi)	Total harmonic distortion	Shall not exceed 7 percent at 500, 800 and 1 600 at RTG position
vii)	Internal noise from the hearing aid in terms of equivalent input noise level	Shall not exceed 30 dB SPL
viii)	Induction coil sensitivity (if telecoil is provided) (at 10 mA/m)	75 dB <i>Min</i>
ix)	AGC characteristics (if applicable):	
	a) Steady state input/output characteristics	a) With the measured and specified curves matched at the point corresponding to 70 dB input SPL, the measured curve at 50 and 90 dB input SPL from the curve specified by the manufacturer for the model by more than ± 5 dB
	b) Dynamic output characteristics	b) The attack and release times shall each be within ± 5 milliseconds or ± 50 percent whichever is larger, of the values specified by the manufacturer for the model
x)	Environmental tests:	
	a) Climatic tests, dry heat at 40°C for 2 h [as per IS 9000 (Part 3)]	a) After all the tests, the hearing aid shall be subjected to the tests specified as acceptance test and shall meet the requirements laid down in the table
	b) Drop test, height of drop 2.0 m on hardwood plane in original individual packing by the manufacturers as intended for end user	b) After one drop from 1.5 m without packing hearing aid shall still be capable of amplification but may not conform to any specifications given in these standards

9.5 The various controls, outlets, etc, should be so provided on the housing as not to interfere with the operation or functioning of the hearing aid in normal use and yet be accessible without difficulty while wearing the aid.

9.6 The microphone should be so mounted and housed as to minimize,

- mechanical transfer of housing noise to the microphone.
- acoustic, magnetic or mechanical coupling between receiver and microphone giving rise to feedback or instability of the amplifier within the rated sensitivity, gain or output.
- mounting microphone at the bottom is not desirable.

9.7 The battery contacts provided should be of corrosion resistant materials.

9.8 Workmanship

Layout of components, wiring and soldering, etc,

should conform to good engineering practices.

9.9 The design of the housing should be such that it is possible to open the housing for maintenance purpose and to adjust the preset controls, if provided without damaging or defacing the housing or the hearing aid components contained therein.

9.10 The housing should be so designed that the method of battery replacement does not require the use of tools, either to open/close the battery compartment or to replace the batteries.

9.11 Information whether the device is to be programmed using trimmer controls or /computer software should be mentioned in the user manual.

9.12 Tone Selector

If a preset tone selector is provided, it shall be easily accessible for adjustment unless taken care off by programs in the hearing aid.

9.13 Each hearing aid should be supplied with at least two different sizes of ear inserts.

ANNEX A*(Clause 2)***LIST OF REFERRED INDIAN STANDARDS**

<i>IS No.</i>	<i>Title</i>	<i>IS No.</i>	<i>Title</i>
10673 : 1983	Sampling Plans and Procedures for Inspection by Attributes for Electronic Items (superseding IS 2612 : 1965)	(Part 1) : 1984	acoustical characteristics of hearing aids
9000 (Part 3) : 1977	Basic environmental testing procedures for electronic and electrical items: Part 3 Dry heat test	(Part 2) : 1984	General measurements for air-conduction hearing aids (superseding IS 3641 : 1976)
10776	Methods of measurement of electro-	4905 : 1968	Additional measurements for hearing aids with induction pick-up coil input
			Methods for random sampling

ANNEX B*(Foreword and Clause 2)***LIST OF REFERRED INTERNATIONAL STANDARDS**

<i>Sl No.</i>	<i>International Standard</i>	<i>Title</i>
1	IEC 60118-7 : 2005	Electroacoustics — Hearing aids — Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes

ANNEX C*(Clause 5.5.2)***MARKING OF CONTROL SETTINGS ON HEARING AIDS****C-0 GENERAL**

C-0.1 The object of this Annex is to provide uniformity in markings used on hearing aids. Because of their small size or for other reasons, marking shall be as given in this Annex are to be adopted.

C-0.2 The markings should be preferably in easily readable characters and aiming on a ready identification for the various control settings.

C-1 BATTERY SWITCH (IF PROVIDED)**C-2 INPUT SELECTION**

If provided, shall be explained in the manual.

C-2.1 Selection

Patient should be able to shift easily between Mic and

Telecoil (if provided), using either,

- a) static switch (like OTM switch); or
- b) momentary switch (press for change).

C-3 TONE CONTROL (IF PROVIDED)

The marking shall be as follows:

Function	: Marking
Normal or no emphasis	: N
Low frequency suppressor	: H or NL

C-4 GAIN CONTROL OR VOLUME CONTROL

The device shall have a gain control (or volume control) whose setting shall be clearly explained in the instruction manual.

C-5 OUTPUT LIMITING CONTROL (IF PROVIDED)

ANNEX D

(Clause 8.1.2)

SAMPLING AND CRITERIA FOR CONFORMITY

D-1 LOT

D-1.1 In a consignment, all the hearing aids of the same category, manufactured from the same material under similar conditions of production shall be grouped together to constitute a lot.

D-1.2 The number of hearing aids to be selected from the lot shall depend upon the size of the lot and shall be in accordance with col 2 of Table 2.

D-1.2.1 These hearing aids shall be selected from the lot at random. In order to ensure the randomness of selection, procedures given in IS 4905 may be followed.

D-2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

All the hearing aids selected from the lot at random according to col 2 and col 3 of Table 2 shall be

subjected to the acceptance tests. A hearing aid failing to meet the requirements of any of these acceptance tests shall be termed as 'defective'. The lot shall be considered as conforming to the requirements of acceptance tests, if the number of defectives found in the sample is less than or equal to the corresponding acceptance number given in col 4 of Table 2, otherwise the lot shall be rejected.

Table 2 Sample Size and Acceptance Number
(Clauses D-1.2 and D-2)

Sl No.	Lot Size	Sample Size	Acceptance Number
(1)	(2)	(3)	(4)
1	Up to 50	8	0
2	51 - 100	13	1
3	101 - 300	20	1
4	301 - 500	32	2
5	501 and above	50	3

ANNEX E*(Foreword)***COMMITTEE COMPOSITION**

Audio, Video and Multimedia Systems and Equipment Sectional Committee, LITD 07

<i>Organization</i>	<i>Representative(s)</i>
Directorate General, Doordarshan, Prasar Bharati, New Delhi	SHRI R. K. SINHA (Chairman)
Ahuja Radios, New Delhi	SHRI A. B. LAL
All India Institute of Speech and Hearing, Mysore	DR S. R. SAVITHRI SHRI AJISH K. ABRAHAM (<i>Alternate</i>)
All India Radio, Prasar Bharati, New Delhi	SHRI YOGENDRA PAL SHRI SANJEEV SAXENA (<i>Alternate</i>)
Artificial Limbs Manufacturing Corporation of India, Kanpur	SHRI A. K. SINGH
ALPS International, New Delhi	SHRI R. N. NARANG
Ali Yavar Jung National Institute for the Hearing Handicapped, Mumbai	REPRESENTATIVE SHRI RAJEEV JALVI (<i>Alternate</i>)
Broadcast Engineering Consultants India Limited, BECIL, Noida	SHRI J. P. NATHANI SHRI K. GEORGE (<i>Alternate</i>)
Bharat Electronics Limited, Bangalore	SHRI SAMEER KUMAR VERMA
Consumer Electronics and Appliances Manufacturers Association, New Delhi	SHRI ANOOP KUMAR SHRI MOHIT VERMA (<i>Alternate I</i>) SHRI ANKAN BISWAS (<i>Alternate II</i>)
Cable Operators Federation of India, New Delhi	LT COL K. K. SHARMA
Directorate of Co-ordination [Police Wireless], New Delhi	SHRI A. K. GUPTA SHRI VENU KUMAR K. M. (<i>Alternate</i>)
Directorate General Doordarshan, Prasar Bharati, New Delhi	SHRI H. K. WADHWA SHRI A. K. JHA (<i>Alternate</i>)
DGAQA, Ministry of Defence, Ghaziabad	REPRESENTATIVE SHRI V. ALAGUMURUGESAN (<i>Alternate</i>)
Directorate General of Supplies and Disposals, DGS&D, New Delhi	SHRI H. R. SHARMA SHRI A. K. RAI (<i>Alternate</i>)
Dish TV India Limited, Noida	SHRI RAJIV KHATTAR SHRI B. SUNDARESHAN (<i>Alternate</i>)
Electronics Corporate of India Limited, Hyderabad	SHRI D. SUDHANAND SHRI D. SRINIVAS (<i>Alternate</i>)
ELCINA Electronics Limited, New Delhi	REPRESENTATIVE SHRI N. S. AHUJA (<i>Alternate</i>)
Electronics Regional Test Laboratory (North), New Delhi	SHRI MAHAVIR PRASAD SHRI MANOJ KUMAR (<i>Alternate</i>)
Institution of Electronics and Telecommunication Engineers, Noida	SHRI R. K. GUPTA
Ministry of Defence, DQA(N), New Delhi	CDR V. KESHAV RAJ SHRI R. L. JAGALLO (<i>Alternate</i>)
National Physical Laboratory, New Delhi	DR MAHAVIR SINGH REPRESENTATIVE (<i>Alternate</i>)
Development Commissioner, Ministry of Micro, Small & Medium Enterprises, New Delhi	SHRI R. K. RAI SHRI M. U. FAROOQ/SATINDER SINGH (<i>Alternate I</i>) SHRI A. K. VERMA (<i>Alternate II</i>)
Reliance Big TV Limited, Navi Mumbai	REPRESENTATIVE SHRI SUDHIR GOSAR (<i>Alternate</i>)
Tata Sky Limited, New Delhi	SHRI YIGIT RIZA MS NANDINI PAUL (<i>Alternate</i>)
Telecommunication Engineering Centre, New Delhi	SHRI U. K. SRIVASTAVA SHRI BAL KISHAN (<i>Alternate</i>)

<i>Organization</i>	<i>Representative(s)</i>
Voluntary Organization Interest of Consumer Education, New Delhi	SHRI H. WADHWA
Wireless Planning and Coordination Wing (WPC Wing), Ministry of Communications & IT, New Delhi	REPRESENTATIVE SHRI SUKH PAL SINGH (<i>Alternate I</i>) SHRI V. K. PANT (<i>Alternate II</i>)
In personal capacity (<i>291, MIG Flats Prasad Nagar, New Delhi 110 005</i>)	SHRI M. M. ASTHANA
In personal capacity (<i>B406, Ram Vihar, Sector 30, Noida, Uttar Pradesh 201301</i>)	LT COL (RETD) V. C. KHARE
BIS Directorate General, New Delhi	SHRI P. RADHAKRISHNA, Scientist F and Head (LITD) [Representing Director General (<i>Ex-officio</i>)]

Member Secretary
SHRI JITENDER KUMAR
Scientist C (LITD), BIS

Panel for Audio Systems, LITD 07/P1

<i>Organization</i>	<i>Representative(s)</i>
Ahuja Radios, New Delhi	SHRI A. B. LAL (<i>Convener</i>)
All India Institute of Speech and Hearing, Mysore	DR S. R. SAVITHRI SHRI AJISH K. ABRAHAM (<i>Alternate</i>)
All India Radio, New Delhi	SHRI R. K. SINGH SHRI ASHISH BHATNAGAR (<i>Alternate I</i>) SHRI DEEPAK MEHROTRA (<i>Alternate II</i>)
ALPS International, New Delhi	SHRI R. N. NARANG SHRI ALOK NARANG (<i>Alternate</i>)
Artificial Limbs Manufacturing Corporation of India, Kanpur	SHRI A. K. SINGH
Ali Yavar Jung National Institute for the Hearing Handicapped, Mumbai	REPRESENTATIVE SHRI RAJEEV JALVI (<i>Alternate</i>)
Broadcast Engineering Consultants India Limited, Noida	SHRI RAVI JAGTAP SHRI RAMIT LALA (<i>Alternate</i>)
Centre for Development of Advanced Computing, Trivandrum	SHRI R. RAVINDRA KUMAR SHRI THOMAS JOSEPH (<i>Alternate</i>)
National Physical Laboratory, New Delhi	SHRI OMKAR SHARMA DR ASHOK KUMAR (<i>Alternate</i>)
3M India Limited, Gurgaon	SHRI VINAY PATHAK MS SIMRAN SHARMA (<i>Alternate</i>)
In personal capacity (<i>B406, Ram Vihar, Sector 30, Noida, Uttar Pradesh – 201301</i>)	LT COL (RETD) V. C. KHARE

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act*, 1986 to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

This Indian Standard has been developed from Doc No.: LITD 07 (3153).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002

Telephones : 2323 0131, 2323 3375, 2323 9402

Website: www.bis.org.in

Regional Offices:

Telephones

Central	: Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	{ 2323 7617 2323 3841
Eastern	: 1/14 C.I.T. Scheme VII M, V. I. P. Road, Kankurgachi KOLKATA 700054	{ 2337 8499, 2337 8561 2337 8626, 2337 9120
Northern	: SCO 335-336, Sector 34-A, CHANDIGARH 160022	{ 260 3843 260 9285
Southern	: C.I.T. Campus, IV Cross Road, CHENNAI 600113	{ 2254 1216, 2254 1442 2254 2519, 2254 2315
Western	: Manakalaya, E9 MIDC, Marol, Andheri (East) MUMBAI 400093	{ 2832 9295, 2832 7858 2832 7891, 2832 7892

Branches: AHMEDABAD. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE. DEHRADUN. FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KANPUR. LUCKNOW. NAGPUR. PARWANOO. PATNA. PUNE. RAJKOT. THIRUVANANTHAPURAM. VISAKHAPATNAM.